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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,380	07/22/2003	Robert Mulroy	06727/012001	1018
21559	7590	09/26/2006	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			WAX, ROBERT A	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/624,380	MULROY ET AL.
	Examiner Robert A. Wax	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 June 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 20-76 is/are withdrawn from consideration.
- 5) Claim(s) 16 is/are allowed.
- 6) Claim(s) 17 and 18 is/are rejected.
- 7) Claim(s) 19 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 10/030,351.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>20050330</u>	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input checked="" type="checkbox"/> Other: <u>Attachment</u>

DETAILED ACTION

Election/Restrictions

1. Claims 1-15 and 20-76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 30, 2006.

Information Disclosure Statement

2. The information disclosure statement filed March 30, 2005 has been considered. Please see the attached initialed PTO-1449s.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims read on fragments of non-glycosylated human alpha-fetoprotein. Thus, the claims read on any fragment of any size not necessarily having

any function at all. The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art. The instant specification is not enabling for claims drawn to fragments having no defined activity.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, (1) the amount of experimentation is large because the number of possible fragments is large; (2) the amount of guidance provided by the specification is zero since fragments are only mentioned but never fully discussed. One

of skill in the art would have no idea what function the fragments might have and, thus, have no idea how to use such fragments. Continuing, (3) the specification is totally devoid of any working examples of fragments, functional or otherwise; as for the next Wands factor, (4) the nature of the invention is a fragment having the same function as full-length α -fetoprotein. The prior art (5) shows that α -fetoprotein is well known but no fragments are known that have the function of the full length protein; (6) the relative level of skill in this art is very high; (7) the predictability of the art is zero since the function of the fragments is unknown. Finally, (8) the claims are enormously broad because of the variability of the fragments and the potential variability of their functions

Based on this analysis, the conclusion that it would require undue experimentation to practice the instant invention is inescapable.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 17 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by

Lichenstein et al.

Lichenstein et al. teach a protein having SEQ ID No.: 6 as their SEQ ID No.: 4. This clearly anticipates claim 17. Please see Attachment B to this Office action which shows the sequence alignment.

7. Claim 17 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by Economou et al.

Economou et al. teach a protein having SEQ ID No.: 6 as their SEQ ID No.: 2. This clearly anticipates claim 17. Please see Attachment A to this Office action which shows the sequence alignment.

Allowable Subject Matter

8. Claim 16 is allowed because the recited mutation is neither taught nor suggested by the prior art.

9. Claim 19 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The fragments all have the mutation recited in claim 16, which are not taught by the prior art, and are therefore allowable.

Conclusion

10. Claim 16 is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Robert A. Wax
Primary Examiner
Art Unit 1653

RAW



US 20030143237A1

(19) United States

(12) Patent Application Publication
Economou et al.

(10) Pub. No.: US 2003/0143237 A1
(43) Pub. Date: Jul. 31, 2003

(54) METHOD AND COMPOSITIONS FOR
TREATING HEPATOCELLULAR CANCER

now abandoned, which is a division of application
No. 09/373,913, filed on Aug. 12, 1999, now aban-
doned, which is a continuation of application No.
PCT/US98/02753, filed on Feb. 13, 1998.

(76) Inventors: James S. Economou, Pacific Palisades,
CA (US); Lisa H. Butterfield, Long
Beach, CA (US); Antoni Ribas
Bruguera, Los Angeles, CA (US)

(60) Provisional application No. 60/339,690, filed on Dec.
12, 2001. Provisional application No. 60/181,966,
filed on Feb. 10, 2000. Provisional application No.
60/038,375, filed on Feb. 13, 1997.

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Pasadena, CA 91101 (US)

(21) Appl. No.: 10/214,725

(22) Filed: Aug. 7, 2002

Related U.S. Application Data

(60) Continuation of application No. 09/781,844, filed on
Feb. 12, 2001, now abandoned.
Continuation of application No. PCT/US01/04539,
filed on Feb. 12, 2001, which is a continuation-in-part
of application No. 09/662,505, filed on Sep. 14, 2000,
now abandoned, and which is a continuation-in-part
of application No. 09/660,252, filed on Sep. 12, 2000,

(51) Int. Cl.⁷ A61K 39/00
(52) U.S. Cl. 424/185.1; 424/93.7

(57) ABSTRACT

A method for preventing or for treating cancer in a mammal,
where the cancer cells express at least a part of an alpha
fetoprotein molecule at the cell surface. The method com-
prises creating an immune response in the mammal to at
least part of the amino acid sequence of an alpha fetoprotein
molecule, where the immune response comprises activating
alpha fetoprotein peptide specific T lymphocytes against the
cancer cells, and where the part of the alpha fetoprotein
molecule is selected from the group consisting of residues
137-145 of SEQ ID NO:2, and residues 325-334 of SEQ ID
NO:2 and a combination of the preceding.

Attachment A

Sequence alignment between SEQ ID 6 and
SEQ ID 2 of 2003/0143237

ADD84895
ID ADD84895 standard; protein; 609 AA.
XX
AC ADD84895;
XX
DT 29-JAN-2004 (first entry)
XX
DE Human alpha fetoprotein (AFP).
XX
KW Cancer; alpha fetoprotein; AFP; cell surface; T lymphocyte;
KW hepatocellular carcinoma; HCC; human; cytostatic.
XX
OS Homo sapiens.
XX
FH Key Location/Qualifiers
FT Region 137. .145
FT /note= "Specifically claimed in Claim 1"
FT Region 325. .334
FT /note= "Specifically claimed in Claim 1"
XX
PN US2003143237-A1.
XX
PD 31-JUL-2003.
XX
PF 07-AUG-2002; 2002US-00214725.
XX
PR 13-FEB-1997; 97US-0038375P.
PR 13-FEB-1998; 98WO-US002753.
PR 12-AUG-1999; 99US-00373913.
PR 10-FEB-2000; 2000US-0181966P.
PR 12-SEP-2000; 2000US-00660252.
PR 14-SEP-2000; 2000US-00662505.
PR 12-FEB-2001; 2001US-00781844.
PR 12-FEB-2001; 2001WO-US004539.
PR 12-DEC-2001; 2001US-0339690P.
XX
PA (ECON/) ECONOMOU J S.
PA (BUTT/) BUTTERFIELD L H.
PA (BRUG/) RIBAS BRUGUERA A.
XX
PI Economou JS, Butterfield LH, Ribas Bruguera A;
XX
DR WPI; 2003-851778/79.
DR N-PSDB; ADD84894.
XX
PT Preventing or treating cancer in a mammal by creating an immune response
PT in the mammal to at least part of the amino acid sequence of an alpha
PT fetoprotein molecule.
XX
PS Claim 3; SEQ ID NO 2; 15pp; English.
XX
CC The present invention relates to a method for preventing or treating
CC cancer in a mammal. The method comprises creating an immune response in
CC the mammal to at least part of the amino acid sequence of alpha
CC fetoprotein (AFP). The cancer cells express at least a part of an alpha
CC fetoprotein molecule at the cell surface. The immune response comprises
CC activating AFP peptide-specific T lymphocytes against the cancer cells.
CC The method is particularly useful for preventing or treating
CC hepatocellular carcinoma (HCC) in humans. The present sequence represents
CC human AFP.
XX
SQ Sequence 609 AA;

Query Match 99.9%; Score 3191; DB 7; Length 609;
Best Local Similarity 99.8%; Pred. No. 3.2e-290;
Matches 608; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

Qy 1 MKWVESIFLIFLLNFTESRTLHRNEYGIASILD SYQCTAEISLADLATIFFAQFVQEATY 60
|||
Db 1 MKWVESIFLIFLLNFTESRTLHRNEYGIASILD SYQCTAEISLADLATIFFAQFVQEATY 60

Qy 61 KEVSKMVKDALTAEKPTGDEQSSGCLENQLPAFLEELCHEKEILEKYGHSDCCSQSEEG 120
|||
Db 61 KEVSKMVKDALTAEKPTGDEQSSGCLENQLPAFLEELCHEKEILEKYGHSDCCSQSEEG 120

Qy 121 RHNCFLAHKKPTPASIPLFQVPEPVTSCEAYEEDRETFMNKFIFYEIARRHPFLYAPILL 180
|||
Db 121 RHNCFLAHKKPTPASIPLFQVPEPVTSCEAYEEDRETFMNKFIFYEIARRHPFLYAPILL 180

Qy 181 WAARYDKIIPSCCKAENAVECFQTKAATVTKELRESSLLNQHACAVMKNFGTRTFQAITV 240
|||
Db 181 WAARYDKIIPSCCKAENAVECFQTKAATVTKELRESSLLNQHACAVMKNFGTRTFQAITV 240

Qy 241 TKLSQKFTKVXFTEIQKLVLDAHVHEHCCRGDVLDCLQDGEKIMSYICCSQQDTLSNKIT 300
|||
Db 241 TKLSQKFTKVNFTEIQKLVLDAHVHEHCCRGDVLDCLQDGEKIMSYICCSQQDTLSNKIT 300

Qy 301 ECCKLTTLERGQCIIHAENDEKPEGLSPNLNRFLGDRDFNQFSSGEKNIFLASFVHEYSR 360
|||
Db 301 ECCKLTTLERGQCIIHAENDEKPEGLSPNLNRFLGDRDFNQFSSGEKNIFLASFVHEYSR 360

Qy 361 RHPQLAVSVILRVAKGYQELLEKCFQTENPLECQDKGEEELQKYIQESQALAKRSCGLFQ 420
|||
Db 361 RHPQLAVSVILRVAKGYQELLEKCFQTENPLECQDKGEEELQKYIQESQALAKRSCGLFQ 420

Qy 421 KLGEYYLQNAFLVAYTKKAPQLTSSELMAITRKMAATAATCCQLS EDKLLACGEGAADII 480
|||
Db 421 KLGEYYLQNAFLVAYTKKAPQLTSSELMAITRKMAATAATCCQLS EDKLLACGEGAADII 480

Qy 481 IGHLCIRHEMTPVNPGVGQCCCTSSYANRRPCFSSLVVDETYVPPAFSDDKFIHKDLCQA 540
|||
Db 481 IGHLCIRHEMTPVNPGVGQCCCTSSYANRRPCFSSLVVDETYVPPAFSDDKFIHKDLCQA 540

Qy 541 QGVALQTMKQEFLINLVKQKPQITEEQLEAVIADFSGLLEKCCQGQEAEQVFAEEGQKLI 600
|||
Db 541 QGVALQTMKQEFLINLVKQKPQITEEQLEAVIADFSGLLEKCCQGQEAEQVFAEEGQKLI 600

Qy 601 SKTRAALGV 609
|||
Db 601 SKTRAALGV 609

United States Patent [19]
Lichenstein et al.

[11] Patent Number: 5,652,352
[45] Date of Patent: Jul. 29, 1997

[54] AFAMIN: A HUMAN SERUM ALBUMIN-LIKE GENE

[75] Inventors: Henri Stephen Lichenstein, Ventura; David Edwin Lyons, Thousand Oaks, both of Calif.; Mark Matsuo Wurzel, New York; Samuel Donald Wright, Larchmont, both of N.Y.

[73] Assignees: Amgen Inc., Thousand Oaks, Calif.; The Rockefeller University, New York, N.Y.

[21] Appl. No.: 222,619

[22] Filed: Mar. 31, 1994

[51] Int. Cl.⁶ C07H 21/02; C07H 21/04; C12P 21/00

[52] U.S. Cl. 536/23.5; 536/23.1; 435/69.1

[58] Field of Search 435/6, 320.1, 69.1; 536/23.1, 23.5, 24.3, 23.2, 24.5; 514/44

[56] References Cited

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Primary Examiner—Eggerton A. Campbell
Attorney, Agent, or Firm—Daniel R. Curry, Ron K. Levy;
Steven M. Odre

[57] ABSTRACT

The invention relates to a novel human serum protein and nucleic acid referred to as AFM, which has one or more activities in common with human serum albumin, human α -fetoprotein, or human vitamin D binding protein and which has an apparent molecular weight by SDS-PAGE of 87 kDa; variants thereof; and related genes, vectors, cells and methods.

12 Claims, 12 Drawing Sheets

Attachment B

Sequence alignment between SEQ ID No. 6
and SEQ ID No. 4 of 5,652,352.

US-08-222-619-4

; Sequence 4, Application US/08222619
; Patent No. 5652352
; GENERAL INFORMATION:
; APPLICANT: Lichenstein, Henri
; APPLICANT: Lyons, David
; APPLICANT: Wurfel, Mark
; APPLICANT: Wright, Samuel
; TITLE OF INVENTION: Afamin: A Human Serum Albumin-Like
; TITLE OF INVENTION: Protein
; NUMBER OF SEQUENCES: 33
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: Amgen Center, Patent Operations/RRC
; STREET: 1840 DeHavilland Drive
; CITY: Thousand Oaks
; STATE: California
; COUNTRY: U.S.
; ZIP: 91320-1789
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Floppy disk
; COMPUTER: IBM PC compatible
; OPERATING SYSTEM: PC-DOS/MS-DOS
; SOFTWARE: PatentIn Release #1.0, Version #1.25
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/08/222,619
; FILING DATE:
; CLASSIFICATION: 435
; INFORMATION FOR SEQ ID NO: 4:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 609 amino acids
; TYPE: amino acid
; STRANDEDNESS: unknown
; TOPOLOGY: unknown
; MOLECULE TYPE: protein

US-08-222-619-4

Query Match 99.9%; Score 3191; DB 1; Length 609;
Best Local Similarity 99.8%; Pred. No. 3.7e-314;
Matches 608; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

Qy 1 MKWVESIFLIFLLNFTESRTLHRNEYGIASILD SYQCTAEISLADLATIFFAQFVQEATY 60
Db 1 MKWVESIFLIFLLNFTESRTLHRNEYGIASILD SYQCTAEISLADLATIFFAQFVQEATY 60

Qy 61 KEVSKMVKDALTAEKPTGDEQSSGCLENQLPAFLEELCHEKEILEKYGHSDCCSQSEEG 120
Db 61 KEVSKMVKDALTAEKPTGDEQSSGCLENQLPAFLEELCHEKEILEKYGHSDCCSQSEEG 120

Qy 121 RHNCFLAHKKPTPASIPLFQVPEPVTSCEAYEEDRETFMNKFIYEIARRHPFLYAP TILL 180
Db 121 RHNCFLAHKKPTPASIPLFQVPEPVTSCEAYEEDRETFMNKFIYEIARRHPFLYAP TILL 180

Qy 181 WAARYDKIIPSCCKAENAVERCQTKAATVTKE LRESSLLNQHACAVMKNFGTRTFQA ITV 240
Db 181 WAARYDKIIPSCCKAENAVERCQTKAATVTKE LRESSLLNQHACAVMKNFGTRTFQA ITV 240

Qy 241 TKLSQKFTKVXFT EIQLVLDVAHVHEHCCRGDVLDCLQDG EKIMSYI CSQ QDTLSN KIT 300
Db 241 TKLSQKFTKVNFTEIQLVLDVAHVHEHCCRGDVLDCLQDG EKIMSYI CSQ QDTLSN KIT 300

Qy 301 ECCKLTTLERGQCIIHAENDEKPEGI SPNLNRFLGDRDFNQFSSGEKNI FLASFVHE YSR 360
Db 301 ECCKLTTLERGQCIIHAENDEKPEGI SPNLNRFLGDRDFNQFSSGEKNI FLASFVHE YSR 360

Qy 361 RHPQLAVSVILRVAKGYQELLEKCFC QTENPLECQDKGEEELQKYIQESQALAKRSCGLFQ 420
Db 361 RHPQLAVSVILRVAKGYQELLEKCFC QTENPLECQDKGEEELQKYIQESQALAKRSCGLFQ 420

Qy 421 KLGEYYLQNAFLVAYTKKAPQLTSELMAITRKMAATAATCCQLSEDKLLACGEGAADII 480
||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||
Db 421 KLGEYYLQNAFLVAYTKKAPQLTSELMAITRKMAATAATCCQLSEDKLLACGEGAADII 480

Qy 481 IGHLCIRHEMTPVNPGVGQCCTSSYANRRPCFSSLVVDETYVPPAFSDDKFIFHKDLCQA 540
||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||
Db 481 IGHLCIRHEMTPVNPGVGQCCTSSYANRRPCFSSLVVDETYVPPAFSDDKFIFHKDLCQA 540

Qy 541 QGVALQTMKQEFLINLVKQKPQITEEYLEAVIADFSGLLEKCCQGQEAEVCFQKLI 600
||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| ||| |||
Db 541 QGVALQTMKQEFLINLVKQKPQITEEYLEAVIADFSGLLEKCCQGQEAEVCFQKLI 600

Qy 601 SKTRAALGV 609
||| ||| |||
Db 601 SKTRAALGV 609